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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,309	02/11/2004	Dilip Tapadiya	TAPADI.003C1	3507

20995 7590 03/28/2007  
KNOBBE MARTENS OLSON & BEAR LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

EXAMINER
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KIDWELL, MICHELE M

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/28/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/28/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

<b>Office Action Summary</b>	Application No. 10/776,309	Applicant(s) TAPADIYA, DILIP	
	Examiner Michele Kidwell	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31,32,34-50 and 99-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31,32,34-50 and 99-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/27/06;9/29/06</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 99 – 101 are rejected under 35 U.S.C. 102(b) as being anticipated by Gottesman (4,834,068).

With reference to claim 99, Gottesman et al. (hereinafter "Gottesman") discloses an irrigation shield comprising a flexible sheet having an elastically enlargeable aperture configured to releasably engage a head of an irrigation nozzle as set forth in col. 4, lines 4 – 17.

As to claim 100, Gottesman discloses an irrigation shield further comprising a latex portion circumferentially attached to the aperture, the latex portion having an elastically enlargeable opening for receiving the irrigation nozzle as set forth in col. 4, lines 6 – 11 and in figure 2.

Regarding claim 101, Gottesman discloses an umbrella shape as set forth in figure 2.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31 and 35 – 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 6,402,724)

With reference to claims 31 and 43 – 47, Smith et al. (hereinafter "Smith") discloses an irrigation kit comprising: a flexible sheet having an aperture (figures 1 and 3 – 5 ) configured to engage an irrigation device and a basin (col. 9, lines 6 – 9) for collecting irrigation fluid used during an irrigation procedure wherein the aperture, in an enlarged state, is configured to fit over a conical splash shield extending distally from a collar attached to a tip of the irrigation device as set forth in col. 3, lines 41 – 52 and col. 4, lines 34 – 38.

The difference between Smith and claim 31 is the provision that the basin is sterilized and made of a biocompatible hypoallergenic material.

It would have been obvious to one of ordinary skill in the art to sterilize the basin of Smith and produce it with a biocompatible hypoallergenic material since the basin of material is used provide safe and effective wound cleansing to remove dirt, gravel, etc. from a wound site. Likewise, it would have been obvious to one of ordinary skill in the art to provide the device with biocompatible, hypoallergenic material in order to prevent an undesirable reaction between the patient and the product.

Furthermore, the use of the basin may be considered to be configured to collect fluid from any body part.

As to claim 35, Smith discloses a flexible sheet having a shape

selected from the group consisting of a circle, a square, a rectangle, a half-circle, a star and a diamond as set forth in figures 1, 3 and 5.

The difference between Smith and claim 36 is the provision that the flexible sheet has a specific thickness.

Smith discloses a flexible sheet that would ultimately have a thickness.

It would have been obvious to one of ordinary skill in the art to modify the thickness of McKinnon in order to determine the most effective product since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range includes only a level of ordinary skill in the art.

Regarding claim 37, Smith discloses an irrigation kit wherein the flexible sheet is configured to have an umbrella shape as set forth in figures 1, 3 and 5.

As to claim 38, Smith discloses an irrigation kit wherein the flexible sheet is pleated to define an umbrella shape as set forth in figures 1, 3 and 5.

The difference between McKinnon and claim 39 is the provision that the flexible sheet has a specific length.

Smith discloses a flexible sheet that has a length as set forth in the figures .

It would have been obvious to one of ordinary skill in the art to modify the length of Smith in order to determine the most effective product since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range includes only a level of ordinary skill in the art.

Regarding claims 40 – 42, see col. 7, lines 39 – 59.

With reference to claim 48, Smith discloses an irrigation kit further comprising a grommet (46) as set forth in col. 7, lines 11 – 14 .

Claims 31 – 32, 34 and 49 – 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greco (US 5,312,385).

With reference to claim 31, Greco discloses an irrigation kit comprising: a flexible sheet having an aperture (4) configured to engage an irrigation device (5); and a basin (6) for collecting irrigation fluid used during an irrigation procedure wherein the aperture, in an enlarged state, is configured to fit over a conical splash shield extending distally from a collar attached to a tip of the irrigation device as set forth in figure 1.

The difference between Greco and claim 31 is the provision that the basin is sterilized and made of a biocompatible hypoallergenic material.

It would have been obvious to one of ordinary skill in the art to sterilize the basin of Greco and produce it with a biocompatible hypoallergenic material since the basin of material because it is well known in the art to sterilize such a device in order to provide enhanced infection control. Likewise, it would have been obvious to one of ordinary skill in the art to provide the device with biocompatible, hypoallergenic material in order to prevent an undesirable reaction between the patient and the product.

With reference to claim 32, Greco teaches a cannula having an adhesive surface as set forth in col. 4, lines 49 – 55.

Regarding claim 34, Greco teaches a flexible sheet that is made from at least one material selected from the group consisting of polyurethane, polypropylene, polyvinyl chloride, and polyvinyl acetate as set forth in col. 4, lines 27 – 31.

As to claims 49 and 50, Greco teaches an irrigation kit comprising a flexible sheet (2) having an aperture (4) configured to engage an irrigation device (5) and a basin (6) that may be configured as claimed as set forth in the figures.

The difference between Greco and claim 49 is the provision that the basin is sterilized and made of a biocompatible hypoallergenic material.

It would have been obvious to one of ordinary skill in the art to sterilize the basin of Greco and produce it with a biocompatible hypoallergenic material since the basin of material because it is well known in the art to sterilize such a device in order to provide enhanced infection control. Likewise, it would have been obvious to one of ordinary skill in the art to provide the device with biocompatible, hypoallergenic material in order to prevent an undesirable reaction between the patient and the product.

With reference to claim 50, Greco discloses a convertible portion (i.e. the opening at the bottom of the funnel – 6). The limitation requiring the convertible portion to be frangible does not patentably distinguish the claimed invention from the prior art. The convertible portion – whether frangible or not, will yield the same results and therefore, the substitution of one type of convertible portion for another is within the level of ordinary skill in the art.

Claim 102 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gottesman et al. (US 4,834,068).

Gottesman discloses a flexible sheet that has a length as set forth in figure 2.

It would have been obvious to one of ordinary skill in the art to modify the length of Gottesman in order to determine the most effective product since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range includes only a level of ordinary skill in the art.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

With respect to the applicant's argument pertaining to claim 99, the examiner provides the disclosure of the elastically enlargeable aperture as set forth in the rejection. The elastically enlargeable aperture is part of the sheet, thereby rendering at least that portion flexible as claimed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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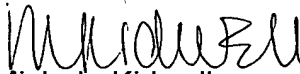
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 571-272-4935. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Michele Kidwell  
Primary Examiner  
Art Unit 3761